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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Criere	017751-030	8894

21839 7590 07/22/2005

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,262	CRIERE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, amendment and remarks dated 5-18-05 is acknowledged.

Claims 1-7 and 9-47 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-18-05 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,895,726 to Curtet et al ('726) in view of U.S. Patent No. 6,074,670 ('670).

'726 teach pharmaceutical compositions containing fenofibrate, co-micronized in an intimate mixture with a solid surfactant (col.1, lines 1). '726 teach micronized particles having a size in the range of less than 15 microns. The composition of '726 further comprises excipients such as polyvinylpyrrolidone, starch, lactose etc (examples) to be filled into the dosage forms such as capsules. With respect to the amount of fenofibrate, formulations A through D contain fenofibrate in amounts as high as 57%. '726 fail to teach cellulose polymer of the instant claims.

'670 teach fenofibrate containing compositions that show improvement over the teachings of '726. The composition of '670 comprises micronized fenofibrate, having a particle size of less than 20 microns or even less than 10 microns (col. 3, lines 65-67), excipients selected from sugars, starches or celluloses such as HPMC (col. 4) and surfactants including sodium lauryl sulfate poloxamer etc (col. 4). '670 teach a ratio of fenofibrate to hydrophilic polymer between 1/10 and 4/1 (col. 5) and also teach 1% to 40% fenofibrate, 5% to 40% hydrophilic polymer, and 0% to10% surfactant (col.6, lines 30-40) by weight of the composition. '670 further suggests the same process of preparing the composition i.e., spraying a suspension of micronized fenofibrate together with a hydrophilic polymer such as cellulose and a surfactant (col. 5, lines 30-35). '670 suggest the same surfactants (including the percentages) and also the excipients of the instant claims. '670 suggest spraying a suspension of fenofibrate (micronized), polymer and a surfactant on an inert core (reads on instant inert granules) improves the bioavailability. Examiner notes that instant specification also is directed to increased bioavailability and is achieved by the same method as that of '670.

'670 fail to teach the claimed percentages of fenofibrate, cellulose and the percentage dissolution (new claim 47). However, '670 teach PVP and celluloses as equally efficient hydrophilic polymers suitable for the invention and suggest using hydrophilic polymer in the range of 5 to 40%. Further, '726 teach high amounts of fenofibrate in their examples. Therefore, absent any evidence to the criticality of the amount of the hydrophilic polymer or the amount of fenofibrate, it would have been within the scope of a skilled artisan at the time of the instant invention to add hydrophilic

cellulose polymer of '670, in an amount of 5% to 40%, to the composition of '670 and prepare the micronized preparation employing the process of '670 because '670 suggests that the presence of the polymer and the process of preparation improves the bioavailability of the active ingredient. Further, '670 recognize that the amount of the binding polymer is dependent upon the amount of active agent and the size of the active agent pellets (col. 2). Accordingly, optimizing the amount of the polymer, depending on the amount of fenofibrate with expectation to obtain the desired dissolution profile of fenofibrate would have been within the scope of a skilled artisan.

Response to Arguments

Applicants' arguments with respect to Deboeck et al are moot, as the rejection has been withdrawn.

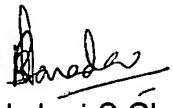
Applicants' arguments regarding the teaching of Stamm '670 have been considered and not found persuasive. It is argued that '670 teach an immediate release formulation. However, instant claims do not exclude such an immediate release composition. Applicants' arguments regarding the examiner's response in the advisory action have been considered and agree with the applicants regarding the MPEP guidelines on the patentability of general differences in the ranges. Applicants argue that '670 unequivocally teach at least 20% of hydrophilic polymer as opposed to claimed 2% to 15%, which is well outside the range and thus goes squarely against the teachings of '670. It is therefore argued that the criticality of the ranges need not be established. '670 do not teach that amounts less than 20% of hydrophilic polymer

should be avoided. Besides, '670 recognize that the amount of binding polymer is dependent upon the amount of fenofibrate and the size of the fenofibrate granule sizes (col.2). Applicants rightly pointed out that the teachings of '670 is an improvement over the fenofibrate composition of US 4,895,726,the improvement being high bioavailability of fenofibrate together with the polymer, surfactants and other excipients. With respect to the argument that the reference fail to teach less than 20%, while '670 teach at least 20% hydrophilic polymer in one embodiment, in col.6, the reference clearly teaches 5% to 40% of hydrophilic polymer. Thus, optimizing the amount of HPMC (of '670) as a binder by routine experimentation is within the scope of a skilled artisan, in the absence of any unexpected result.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 18, 2005